IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

Case No. 14 C 1748	
MDL No. 2545	

CASE MANAGEMENT ORDER No. 116 (rulings on motions in limine in Myers v. AbbVie Inc. et al., Case No. 15 C 1085)

MATTHEW F. KENNELLY, District Judge:

Arthur Myers has sued AbbVie Inc. and Abbott Laboratories Inc. (AbbVie), alleging that its testosterone replacement therapy (TRT) drug, AndroGel, caused him to suffer pulmonary emboli in February 2008. Pulmonary emboli are sudden blockages of blood vessels in the lungs. Myers asserts that AbbVie marketed AndroGel in a misleading manner by representing that it is safe and effective for treating age-related hypogonadism—low levels of testosterone in the blood, and related symptoms, arising out of the normal male aging process. Myers also asserts that AbbVie failed to adequately warn that AndroGel could cause venous thromboembolic (VTE) injuries, like pulmonary embolism or deep-vein thrombosis.

Myers's case is the fifth "bellwether" case in this multidistrict litigation proceeding to go to trial. The Court has issued rulings on motions *in limine* in each of the prior cases, including in three where AbbVie was a defendant. See In re Testosterone

Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings, No. 14 C

1748, 2017 WL 5029601 (N.D. III. Nov. 3, 2017) (Holtsclaw MIL Ruling); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 2313201 (N.D. III. May 29, 2017) (Prior AbbVie MIL Rulings); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2018 WL 305503 (N.D. III. Jan. 6, 2018) (Nolte MIL Ruling); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2018 WL 1316724 (N.D. III. Mar. 14, 2018) (Mitchell II MIL Ruling).

At the pretrial conference on May 2, 2018, the Court adopted certain prior rulings that Myers and AbbVie sought to reaffirm. The parties have also moved to exclude additional items of evidence, and the Court rules on those motions as follows.

A. Evidence AbbVie has moved to exclude

1. Evidence of AbbVie's knowledge and conduct after February 2008

AbbVie contends that whether it "knew or reasonably should have known of the risk of VTE injury must be judged by the information available in February 2008," when Myers had his pulmonary emboli (PE). Defs.' Mot. at 3. Accordingly, AbbVie seeks to exclude evidence relating to the 2014 VTE label change, evidence relating to the 2015 label changes, and other post-February 2008 documents and testimony. AbbVie acknowledges that the Court has denied similar motions in previous bellwether trials, including in *Nolte*, a VTE case where, as here, Arizona law governed the substantive claims. But AbbVie contends that differences in Myers's case justify departures from those rulings.

First, AbbVie argues that although there was a strict liability design defect claim

in *Nolte*, there is no such claim in Myers's case. Myers effectively confirmed this at the May 2, 2018 pretrial conference but argued that he has brought information defect claims arising in both negligence and strict liability. For reasons stated on the record at the pretrial conference, the Court agrees. Unlike for a strict liability design defect claim, Myers cannot introduce post-February 2008 evidence to prove AbbVie's knowledge and conduct for purposes of his information defect claims, except to the extent that evidence bears on AbbVie's knowledge as of February 2008. *See Powers v. Taser Int'l, Inc.*, 217 Ariz. 398, 404, 174 P.3d 777, 783 (Ct. App. Ariz. 2007) (stating that even for strict liability information defect claims, information regarding what "was known or knowable" to manufacturers is measured "at the time of manufacture and distribution").

Nevertheless, as discussed below, the evidence that AbbVie seeks to exclude is admissible for other purposes.

Second, AbbVie argues that an Arizona product liability statute, A.R.S. § 12-686, requires the Court to exclude post-February 2008 labeling evidence. *See* Defs.' Mot. at 3-6. AbbVie cites one case for the proposition that federal courts apply A.R.S. § 12-686, even though the statute sets forth evidentiary rules. *See Walton v. Bridgestone / Firestone Inc.*, No. CV-05-3027-PHX-ROS, 2009 WL 2778441, at *8-9 (D. Ariz. Jan. 16, 2009). The Court is inclined to disagree; it is settled law that the Federal Rules of Evidence govern in federal court, even in diversity cases where the substantive rule of decision is supplied by state law. *See, e.g., Schrott v. Bristol-Myers Squibb Co.*, 403 F.3d 940, 943 (7th Cir. 2005). But even assuming federal courts apply A.R.S. § 12-686, the statute does not bar the labeling evidence. Arizona courts have construed A.R.S. § 12-686 to operate in the same manner for post-*sale* remedial measures as Arizona Rule

of Evidence 407—which is identical to its federal counterpart—operates for post-*injury* remedial measures. *See Readenour v. Marion Power Shovel*, 149 Ariz. 442, 446, 719 P.2d 1058, 1062 (1986). This Court has previously held that Rule 407's exclusion of subsequent remedial measures does not extend to FDA-mandated label changes. Prior AbbVie MIL Ruling, 2017 WL 2313201, at *2. Under *Readenour*, the result is the same under A.R.S. § 12-686.

Having addressed AbbVie's threshold arguments for excluding post-February 2008 evidence of knowledge and conduct, the Court considers its remaining arguments.

i. 2014 VTE label change (and related discussions)

AbbVie seeks to exclude evidence regarding the 2014 VTE label change pursuant to Rules 401 and 403. AbbVie acknowledges the Court's prior ruling that post-injury label changes "can be relevant on the question of what a prescribing physician would have done if the drug's label had been different." See Defs.' Mot. at 3 (quoting Nolte MIL Ruling, 2018 WL 305503, at *8). But AbbVie contends that the 2014 VTE label changes are irrelevant for this purpose in Myers's case because his prescribing physician, Dr. Michaela Tong, testified that the subsequent labeling "would have had no impact on her prescription decision in 2007." Defs.' Mot. at 4. In response, Myers cites Dr. Tong's testimony that had she been told in 2007 of AndroGel's potential to increase the risk of heart attacks and strokes, particularly in patients who had underlying risk factors, she would have discussed this information with Myers. Although this testimony, strictly speaking, concerns the 2015 label changes, it indicates that the point is not as clear-cut as AbbVie contends.

Separately, the Court has ruled in prior bellwether trials that subsequent label

changes are relevant on the issue of causation to the extent they reflect the FDA's views on AndroGel's ability to cause heart attacks. Prior AbbVie MIL Rulings, 2017 WL 2313201, at *2. The same logic extends to VTE causation. AbbVie, however, contends that evidence regarding the 2014 VTE label change is irrelevant for this purpose because, it contends, this evidence shows that the FDA actually "lacked a belief that AndroGel caused VTEs." Defs.' Mot. at 4. AbbVie points to the fact that the FDA "initially propos[ed] language that suggested a causal link between testosterone therapy and VTEs," but later removed the causation language and "approved a labeling change that did not include any causation warning at all." Defs.' Mot. at 4. AbbVie also cites a document from May 2014 in which the FDA indicated that a "direct causality link" between testosterone replacement therapy and VTE could not be made at the time. Defs.' Mot. at 4. Although this may reflect uncertainty on the FDA's part, the FDA nevertheless insisted upon adding information about VTE risk to the label. Thus the label change does, in fact, bear on the causation question. The Court is not persuaded that the probative value of the evidence would be substantially outweighed by the risk of wasting time or of "confus[ing] the jury about the date by which AbbVie's conduct must be judged." Defs.' Mot. at 5.

ii. 2015 label changes (and related discussions)

AbbVie seeks to exclude evidence regarding the 2015 label changes pursuant to Rules 402 and 403. First, based on Dr. Tong's testimony discussed above, AbbVie argues that this evidence is irrelevant regarding whether Dr. Tong would have changed her prescribing practices had AndroGel's label been different. When asked about the 2015 label, however, Dr. Tong stated that she would have discussed with Myers the

information in the label about an increased risk for strokes. Because a thromboembolism can cause a stroke, and because a reasonable jury could credit Dr. Tong's testimony that she would have had a different discussion with Myers had the label contained different information, evidence regarding the 2015 label changes is relevant and admissible to how Dr. Tong might have changed her prescribing practices.

With respect to the FDA's views on causation, AbbVie seeks to exclude evidence regarding "the removal of 'idiopathic' in the secondary hypogonadism paragraph."

Defs.' Mot. at 5. The Court denies AbbVie's motion in this regard because according to AbbVie's endocrinology expert, Myers had a form of idiopathic hypogonadism. AbbVie also seeks to exclude "an addition to 'Limitations of use' stating that 'Safety and efficacy of AndroGel 1% in men with 'age-related hypogonadism' (also referred to as 'late-onset hypogonadism') have not been established." Defs.' Mot. at 5. AbbVie argues that this evidence is irrelevant because "this is not an 'age-related hypogonadism' case." *Id.* at 6. AbbVie, for example, states that Myers began taking AndroGel when he was 37 and had his PE when he was 42. *Id.* at 5-6. Furthermore, according to AbbVie, there is no evidence that Myers's testosterone was low because of his age, yet there *is* evidence—including Myers's comorbid conditions—that Myers's doctors did *not* prescribe AndroGel for age-related hypogonadism.

The Court disagrees with AbbVie's analysis. As discussed when the Court found this evidence admissible in *Nolte*, the prior label contained a warning about AndroGel's efficacy in patients over 65 as compared to younger patients, whereas the 2015 label stated that "safety and efficacy had not been established *at all* in men with age-related hypogonadism, *regardless of age*." Nolte MIL Ruling, 2018 WL 305503, at *8

(emphasis added). AbbVie has presented no evidence that Myers was too young to have age-related hypogonadism or that the 2015 label was not directed toward men under a certain age. Additionally, as Myers notes, his doctor prescribed AndroGel to treat symptoms typically associated with aging: fatigue and problems with libido.

Finally, as the Court understands Myers's argument, his hypogonadism would be considered non-classical even if comorbid conditions like morbid obesity caused his low testosterone levels. And in connection with the 2015 label changes, the FDA told AbbVie that the indication for "all approved testosterone replacement therapies [should] be limited to *classical* hypogonadism." Pl.'s Opp. at 6-7 (emphasis added). Because Myers took AndroGel for a non-indicated purpose, the FDA's position on VTE causation vis-à-vis the 2015 label changes is relevant. And its probative value would not be substantially outweighed by its claimed potential to confuse the jury about the appropriate time frame in which to judge AbbVie's conduct. The time frame can be, and is appropriately, dealt with via the Court's instructions to the jury.1

c. Other post-February 2008 evidence of AbbVie's knowledge and conduct

AbbVie has moved to exclude of documents on Myers's exhibit list that post-date February 2008. Defs.' Mot. at 6. In its motion, AbbVie discusses three specific documents: a June 2015 advertisement for AndroGel 1.62%, a 2012 e-mail discussing the "Glueck" article, and comments AbbVie made in 2010 about AndroGel sales

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¹ AbbVie also states that "[t]he 2015 label change does not tend to establish a link between testosterone replacement therapy and VTE," Defs.' Mot. at 6, but does not support this argument with any analysis. The Court thus declines to consider it. See Crespo v. Colvin, 824 F.3d 667, 674 (7th Cir. 2016) ("[P]erfunctory and underdeveloped arguments, and arguments that are unsupported by pertinent authority, are waived.").

materials. The Court has previously ruled that sales and marketing materials relate to plaintiffs' contentions regarding off-label marketing and are "generally admissible to show AbbVie's intent, motivation, and knowledge with respect to marketing." *See, e.g.*, Prior AbbVie MIL Rulings, 2017 WL 2313201, at *5. This ruling applies with equal force in Myers's case. Separately, AbbVie's commentary on the post-February 2008 Glueck article relates to a retrospective analysis of VTE risk signals that AbbVie conducted. That analysis included information from 2003 to 2008. AbbVie's commentary on the Glueck article is therefore relevant regarding whether AbbVie "should have detected a [VTE] signal prior to [Myers's] injury." Pl.'s Opp. at 7. Finally, the Court is not persuaded that the probative value of any of this evidence is substantially outweighed by the risk of confusion or wasting trial time.

d. Testimony by Dr. Nader Khan

AbbVie argues that the Court should exclude testimony from Dr. Nader Khan, AbbVie's Product Safety Team Leader for AndroGel. AbbVie contends that because Dr. Khan did not join AbbVie until 2012 and was not responsible for TRT products in his prior employment, his "only personal knowledge begins in 2012," and it should not be imputed to AbbVie in 2008. Defs.' Mot. at 7. But Dr. Khan's testimony shows that he performed a retrospective analysis of VTE signal detection that included data from 2004 to 2007. Although AbbVie contends that Dr. Khan's testimony "will be confusing and misleading to the jury, particularly in the context of [Myers's] negligence claims," the Court concludes that Dr. Khan's testimony can shed light on those very claims, including the issue of whether AbbVie should have detected a VTE safety signal before Myers's PE. The Court declines to preclude Dr. Khan's testimony.

2. Causation opinions from treating physicians

a. Dr. Lorie Loreman

AbbVie seeks to exclude deposition testimony from Dr. Lorie Loreman that Myers's "use of hormonal therapy" was a "contributing factor" to his PE. Defs.' Mot. at 8. "An opinion about the specific cause of the plaintiff's injury is undoubtedly an expert opinion requiring disclosure under Federal Rule of Civil Procedure 26(a)." Prior AbbVie MIL Rulings, 2017 WL 2313201, at *10. Myers did not disclose Dr. Loreman as an expert, and Dr. Loreman—who treated Myers for his PE in February 2008—did not state in her contemporaneous notes that AndroGel was a "contributing factor" to Myers's PE. Myers was therefore required to disclose Dr. Loreman's opinion pursuant to Rule 26(a)(2). But this was harmless, because AbbVie itself elicited this testimony during Dr. Loreman's deposition and had a full and fair opportunity to depose Dr. Loreman ion the subject. See Fed. R. Civ. P. 37(c)(1) (party barred from using information or witness not properly disclosed under Rule 26(a) "unless the failure was substantially justified or is harmless") (emphasis added); see also Nolte MIL Ruling, 2018 WL 305503, at *7 (citing same).

AbbVie separately argues that Dr. Loreman's opinion is inconclusive and therefore does not pass muster under Rule 702. The Court disagrees. Dr. Loreman testified that "any hormonal type therapy can increase blood clots," Ex. L to Defs.' Opp. (Loreman Dep. 41:4-5), and this reasoning, which has substantial support in other evidence that Myers will offer, provides a sufficient basis for Dr. Loreman's testimony. The Court overrules AbbVie's motion to exclude this testimony by Dr. Loreman.

b. Dr. John Bibb

For the reasons stated in open court at the final pretrial conference on May 2, 2018, the Court grants AbbVie's motion to redact from Dr. Bibb's September 2008 treatment notes his statement that Myers "was on testosterone which may be a contributing factor" to the PE. To avoid misleading the jury, however, Dr. Bibb's statements in the same records about other contributing factors should also be redacted.

3. Sampling of AndroGel

Myers has stipulated not to offer any evidence of sampling of AndroGel, so AbbVie's request to bar such evidence is moot.

4. Supplemental opinions by certain plaintiff's experts

Myers will not be calling Dr. David Kessler to testify at trial, so AbbVie's motion to bar the opinions contained in his April 16, 2018 supplemental report is moot. In addition, Myers has stated that he does not intend to rely upon Dr. Peggy Pence's April 2018 supplemental report, so AbbVie's motion to preclude the opinions in that report is similarly moot.

5. AbbVie's financial condition

As stated at the final pretrial conference, the admission of evidence regarding AbbVie's financial condition—which Myers is offering on the subject of punitive damages—should be handled as it has been in prior bellwether trials regarding AbbVie (that is, via stipulation regarding the company's net worth).

B. Evidence Myers has moved to exclude

1. Prior motion in limine rulings

As indicated earlier, the Court reaffirms its prior *in limine* rulings referenced by the parties.

2. Myers's opinion regarding the cause of his pulmonary emboli

As stated at the final pretrial conference, AbbVie may not seek to elicit from Myers his opinion regarding what caused his pulmonary emboli. If AbbVie comes to believe during the trial that Myers has opened the door to this evidence, it should raise the point with the Court outside the jury's presence.

3. Myers's opioid use

Myers moves to preclude AbbVie from arguing that he has improperly used or abused opioids or other pain killers. AbbVie contends that such evidence "is relevant to his risk characteristics." Defs.' Opp. at 5. AbbVie likewise argues that it should be able to use this evidence to rebut Myers's argument that he would not have taken AndroGel had AbbVie issued a proper warning.

The Court has excluded similar evidence in prior bellwether trials due to its low probative value and its significant potential to confuse the jury or cause unfair prejudice, and AbbVie has offered no viable reason to change course here. Holtsclaw MIL Ruling, 2017 WL 5029601, at *7 (stating that a "plaintiff's willingness to take [an] unrelated drug had little probative value on the issue of whether he would take a TRT drug when accompanied by a stronger warning label"); see also, e.g., Prior AbbVie MIL Rulings, 2017 WL 2313201, at *11 (rejecting AbbVie's argument that Mitchell's use of alcohol and marijuana "demonstrates his penchant for taking risks").

4. Evidence regarding Myers's noncompliance with other medications

Myers argues that the Court should exclude evidence or opinions that he has a character for being a noncompliant patient. AbbVie's expert Dr. Helena Rodbard, for example, states that according to Myers's medical history, "he has not been compliant with many of the recommendations of his health care providers, including recommendations related to compliance with medications." Pl.'s Mot. at 5. Dr. Rodbard later opines that based on this information, "it is unlikely that Mr. Myers took AndroGel as prescribed." *Id.* at 6. Similarly, it opposing Myers's motion, AbbVie states that evidence about Myers's noncompliance "relates squarely to [his] decision-making conduct on relevant health issues." Defs.' Opp. at 8.

These arguments run afoul Federal Rule of Evidence 404(b), which states that evidence of "other act[s] is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). AbbVie does not tackle Rule 404(b) head-on but rather argues that "medical history" is not character evidence within the meaning of Rule 404. The cases AbbVie relies upon are unpersuasive, however, because (among other reasons) the courts in those cases considered evidence of diagnosed "organic delusional disorder" and of documented "hypoglycemic episodes." *See Bemben v. Hunt*, No. 93 C 509, 1995 WL 27223, at *2 (N.D. III. Jan. 23, 1995); *Phillips v. Gen. Motors Corp.*, No. Civ. A. 99-3423, 2000 WL 1407896, at *3 (E.D. La. Sept. 25, 2000). Evidence regarding actual medical conditions is hardly comparable to purported history of disregarding medical advice or prescription guidelines. The Court also notes that evidence regarding Myers's actual usage of AndroGel is readily available via his prescription refill records, as

AbbVie itself discusses in its response to Myers's motion. See Defs.' Opp. at 6-7. With this in mind, the purported inference that AbbVie wishes to draw from Myers's use of different medications has only marginal probative value. The Court excludes evidence of Myers's non-AndroGel medication history under Rules 404 and 403.

AbbVie also argues that evidence of Myers's noncompliance is relevant regarding causation for PE, hypogonadism, and underlying risk factors for PE such as obesity and diabetes. But AbbVie does not cite any testimony, expert or otherwise, that directly supports these theories. The probative value of Myers's alleged noncompliance as related to causation is extremely low, and it is substantially outweighed by the risk of unfair prejudice and confusion.

5 & 6. Cumulative expert testimony; argument about number of experts

As discussed at the final pretrial conference on May 2, the Court precludes the testimony of Dr. Marais as unduly cumulative of other expert causation testimony that AbbVie intends to offer.

AbbVie represents that it will not argue or use exhibits that attempt to count or compare the number of witnesses testifying for each side on particular topics, so Myers's motion to preclude such argument is moot.

7. Evidence that Dr. Tong specifically warned Myers about VTE risk

Myers asks the Court to preclude AbbVie from eliciting from its experts or arguing to the jury that Dr. Tong provided Myers a specific warning about VTE events outside of the context of VTE events associated with increases in hematocrit. The Court denies the motion; this matter largely concerns weight and is appropriately left to cross-examination and argument.

8. Argument that Myers suffered deep vein thrombosis

Myers moves to preclude AbbVie from arguing or implying that he had a DVT.

Myers has a family history of DVT and visited a doctor on two occasions for leg pain,
but he was never diagnosed with a DVT. AbbVie states that it will not argue otherwise
but that it should be allowed to present evidence that Myers told his physician on
multiple occasions that he was concerned about DVT. This evidence, AbbVie argues, is
relevant to Myers's knowledge of VTE risk factors, including family history. AbbVie also
contends that the evidence is relevant to its statute of limitations defense.

AbbVie will be permitted to elicit anything Myers told a doctor about prior family history of DVT, provided that AbbVie can lay a foundation with testimony that family history is a risk factor for VTE. But AbbVie may not elicit any expression of concern by Myers that he himself had a DVT because Myers is not a doctor and cannot appropriately provide self-diagnosis testimony. *See, e.g., Smith v. Garcia*, No. 15-CV-10105, 2018 WL 461230, at *8 (N.D. III. Jan. 18, 2018) ("Plaintiff will not be allowed to (1) provide a medical diagnosis of her injuries, or (2) testify that the alleged beating proximately caused her medical problems, because this goes beyond lay testimony based on Plaintiff's rational perceptions.").

9. Evidence that prescribing physicians were negligent

AbbVie states that it will not contend that Myers's treating physicians were negligent or committed malpractice in prescribing TRT for him, so Myers's motion to preclude this is moot. AbbVie may introduce testimony tending to show that risk factors for Myers's VTE were not adequately managed, as the Court has ruled in prior trials.

10. Evidence regarding FDA's 1997 medical officer review of Testoderm

Myers asks the Court to preclude AbbVie from introducing into evidence or otherwise discussing the FDA's 1997 medical officer review of Testoderm, another TRT drug. Myers argues that the probative value of the evidence, if any, is low because the document relates to a non-AbbVie product; it is unclear whether the FDA reviewers or the product sponsors made "certain statements"; and the "basis of certain statements" is unknown. Pl.'s Mot. at 13. By contrast, Myers contends, the risk of unfair prejudice and confusion is high.

The Court denies Myers's motion. The Court notes that AbbVie introduced the 1997 review with no objection from plaintiffs in three prior bellwether trials and that AbbVie likewise discussed this document extensively—also with no objection from plaintiff—in a fourth bellwether trial. Myers has provided no rationale specific to his case that justifies exclusion. Myers takes issue with the fact that the document relates to a non-AbbVie product, but it appears that AbbVie plans to use the document to show the size of the TRT market in 1997 and to "rebut [Myers's] argument that TRTs have been approved for only rare conditions." Defs.' Opp. at 15. AbbVie used the 1997 review for these same purposes in the prior trials. And although Myers calls into question the origin and basis of "certain statements" in the 1997 review, the Court cannot rule on this argument without specific examples. The Court overrules Myers's motion.

11. Evidence of IMS data from 2010 to 2018

Myers moves to exclude IMS data from 2010 to 2018. The data, which appears to represent the number of AndroGel prescriptions and the total market for TRT, is

organized into spreadsheets that do not indicate the data's original source(s). Myers

argues that the data is not relevant to any issue in the case and is unfairly prejudicial;

AbbVie argues that the data is relevant if Myers is permitted to offer post-2008

evidence.

Neither side has done a particularly good job on this issue. Myers makes little

effort to explain why the evidence is irrelevant or unfairly prejudicial, and AbbVie offers

no explanation regarding what it intends this evidence shows that might be relevant.

The Court also believes that it may have ruled on this evidence in connection with one

or more prior trials, but neither side has cited any of those rulings. Ruling on this issue

is deferred pending further argument during trial.

12. Undue emphasis on Myers's residence in Arizona

Excessive questioning or argument concerning the fact that Myers lives in and

was treated in Arizona is barred. The case is being tried here because of the creation

of the MDL proceeding and the parties' *Lexecon* waivers, and in any event venue would

be appropriate here given AbbVie's residence in this district. The Court will deal with

questioning or argument that runs afoul of this ruling by a prompt curative instruction

that explains to the jury why Myers's state of residence has no bearing on any issues

the jury has to decide.

United States District Judge

Date: May 5, 2018

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